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Lawrence M Lavin Jr Esq  
Monsanto Company  
Patent Department E2NA  
800 N Lindbergh Blvd  
St Louis, MO 63167

EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/637,086

Applicant(s)

FINCHER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Claims 1 and 10-11 are pending.

***Claim Rejections - 35 USC § 101***

Claim 1 is again rejected and new claims 10 and 11 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicant's arguments filed 7/23/02 have been fully considered but they are not persuasive. Applicant argues that the claimed nucleic acids are useful for isolation of genes, detection of other nucleic acid molecules, determining an Expression Response, and genetic mapping. Applicant further cites 20 USPQ2d 1094, 1100 (Fed. Cir. 1991) as support for the argument that the examiner's position that "the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" is wrong as a matter of law. In response, it is noted the specification teaches only general uses (purposes), but does not teach any specific "purpose" for the elected sequence. The uses argued above are ones which are applicable to the general class of nucleic acids and are not specific to the SEQ ID NO: elected. It is well known in the art that polynucleotides, including others than those recited in the instant claims, can be used in hybridization assays to detect other nucleic acid sequences. A nucleic acid molecule may have utility based on its use as a marker or probe for or related to a specific disease condition or gene known to be correlated with a disease condition (e.g. probes for Huntington's chorea, cystic fibrosis, etc.); however, no correlation between the elected SEQ ID NO: and a specific disease condition is taught by the instant specification. With regard to genetic mapping and determining an Expression Profile, applicant is reminded that a "use" to do

further research (i.e. to establish a correlation between a disease and a gene, or to determine expression patterns in particular tissues) is not a specific, substantial and credible utility under 35 USC 101. For these reasons, the general utilities taught by the specification and argued by applicant do not constitute a specific, substantial, and credible utility for the claimed SEQ ID NO's.

Applicants also argue that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. However, the fact situation in the instant application is not analogous to applicants' microscope or golf club examples. Applicant cites several court cases in the argument regarding credibility. With regard to *In re Ziegler* (20 USPQ2d 1600, 1603), it is noted that the court decided that "Ziegler did not disclose any practical use for the polypropylene or its film". Again, this fact pattern is different from that of the instant application. With regard to *In re Brana* (34 USPQ2d 1436, 1441), the utility of Brana's compounds was based on the activity of the claimed compounds against lymphocytic leukemia, as compared to known compounds with similar activity. Applicant should note that Brana's compounds had established activity (as shown in examples) against a known disease. Similarly, in *Cross vs. Iizuka* (224 USPQ 739, 742), the compounds claimed were shown to have enzyme inhibitory activity related to a known therapeutic use. The instant specification does not disclose any correlation between the elected nucleic acid sequence and a known disease or disorder, therefore SEQ ID NO: 1 can not be said to have utility for the same reasons given in the Brana or Cross vs. Iizuka cases. While the examiner must treat as true any statement of fact made by an applicant unless countervailing evidence can be provided, as argued by applicant, no statements regarding a "practical" utility,

other than those already addressed above, have been made by applicant with regard to the elected nucleic acid sequence.

For the reasons set forth above and previously set forth, the examiner maintains that the claims lack utility, therefore the rejection of claim 1 is maintained and claims 10-11 are rejected.

Claims 1 and 10-11 are also rejected under 35 U.S.C. 112, first paragraph for not being enabled.

Applicant's arguments filed 7/23/02 have been fully considered but they are not persuasive. Applicant argues that as the claimed nucleic acid sequences have utility, they are enabled. This enablement rejection is linked to the utility rejection, as previously set forth. As the utility rejection is maintained, the enablement rejection is also maintained. Arguments set forth on page 10 of the response with regard to this enablement rejection will be held in abeyance until the utility rejection is overcome.

***Claim Rejections - 35 USC § 112, 1st paragraph***

Claim 1 is again rejected, and new claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 7/23/02 have been fully considered but they are not persuasive. Applicants present various arguments and recites several court cases to support that a claim may be broader than specifically taught embodiments and that the specification

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need not recite every sequence represented by the claim. In addition, applicants argue that the specification provides a detailed chemical structure; i.e. SEQ ID NO: 1m therefore any modification thereof may be readily envisioned by one of the skill in the art. In response, it is noted that although claims may be broader than embodiments specifically taught by the specification, the specification must nonetheless fully and completely describe the invention such that it is clear that applicants were in possession of the claimed inventions at the time of filing. It is clear, and the previous office action stated, that sequences consisting of SEQ ID NO: 1 are fully described by the instant specification. However, as previously set forth, sequences which comprise SEQ ID NO: 1 encompass a large variety of structures which are not fully and completely described by the instant specification. The specification teaches on page 20 that an embodiment of the claimed invention includes homologs from other plant, fungi, mammals, bacteria, and algae, and teaches that such homologs may have as little as 25% identity with a disclosed SEQ ID NO. A sequence which is 75% DIFFERENT from SEQ ID NO: 1 is a very different structure from that of SEQ ID NO: 1. For these reasons, the examiner maintains that the variety of structures embodied in the claims is not fully described by the instant specification and that one skilled in the art would not be able to readily envision the members of the genus represented by the claims, therefore the rejection of claim 1 is maintained and claim 10 is rejected.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

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A nucleic acid molecule or fragment thereof which encodes a cotton protein or fragment thereof is not described by the originally filed specification. The instant specification discloses on page 1 that the instantly claimed nucleic acids encode cotton proteins, but is silent with respect to any specific proteins encoded. The specification does not disclose that SEQ ID NO: 1 actually encodes any protein or peptide, nor does the specification disclose an open reading (ORF) or other evidence that SEQ ID NO: 1 does, in fact, encode a polypeptide of any kind. SEQ ID NO: 1 comprises at least two putative start codons (ATG's), but it is unknown which of these represents the start of an ORF, or if the sequence actually encompasses a functional ORF (i.e. one which includes both a start and stop codon in the same reading frame). In addition, while the nucleic acid sequence was isolated from cotton, the specification does not disclose whether a protein or peptide encoded by SEQ ID NO: 1 is specific to cotton, or may be one which is found in a variety of organisms. As the specification does not disclose any protein or peptide encoded by SEQ ID NO: 1, particularly one which is known to be specific to cotton, claim 1 is rejected for lack of written description.

### ***Conclusion***

Claims 1 and 10-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703)


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308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

  
Marjorie A. Moran  
Examiner  
Art Unit 1631

October 20, 2002